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BIOPESTICIDE INDUSTRY ALLIANCE

Opportunities for

~~Challenges to~~ Commercialization of Biopesticides

Microbial Biocontrol of Arthropods, Weeds and Plant Pathogens: Risks, Benefits and Challenges

November 28-December 1, 2010

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Bill Stoneman

Executive Director, Biopesticide Industry Alliance (BPIA)

Regulatory Consultant:	**Prophyta Biologischer Pflanzenschutz**
	JET Harvest Solutions
	Becker-Underwood Inc.
	Sylvan Bio
	Bayer CropScience
	EMD Crop BioSciences
	others…
Manufacturing /Development Consultant:	**Sylvan Bio**
	Osprey Biotechnics

Organic Materials Review Institute (OMRI) Board of Directors

Independent Organic Inspector - USDA-NOP

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IRS – 501(c)(6) Organization

Membership: 56

Industry - Biopesticide Developers/marketers/manufacturers *Certis, Valent BioSciences, NuFarm, BioSafe, BioWorks, Bayer CropScience, Becker –Underwood, Becker Microbials, Prophyta Biologischer Pflanzenschutz and many others…*

Ad Hoc – Service companies (Regulatory Agents, testing laboratories, etc.)

Individual s – researchers and consultants, etc..

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10th
2000 ANNIVERSARY 2010

Outline of my approach

1. Definition of Biopesticides – as defined by BPIA
2. Lack of new chemistries and organic demand are new driving factors to the development and growth of our industry – **There are opportunities**.
3. The chemical v. biological paradigm
4. Money and organizational sustainability
5. Making biopesticides work better
6. BPIA – who we are and our strategies for promotion of biological pesticides

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What are biopesticides?

There may be some confusion about what biopesticides are…

BPIA defines biopesticides: as those organisms or compounds registered as pesticides by agencies such as the US EPA under the BPPD (Biopesticide Pollution Prevention Division) with the exception of PIPs (Plant Incorporated Pesticides)

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What are biopesticides

Microbial (e.g., bacteria, virus, fungus)

Biochemical (e.g. plant extracts (some), pheromones, fatty acids, organic acids, hydrogen peroxide, others…) - *nontoxic mode of action* to the pest, plant pathogen, weed, etc… 25B products are not registered as biological pesticides

Note: Spinosad (pure compound from the microbe *Saccharopolyspora spinosa*) and pyrethrum (plant extract) have organic formulations, but are registered as chemicals because of their (neuro)toxic mode of action to the pest)

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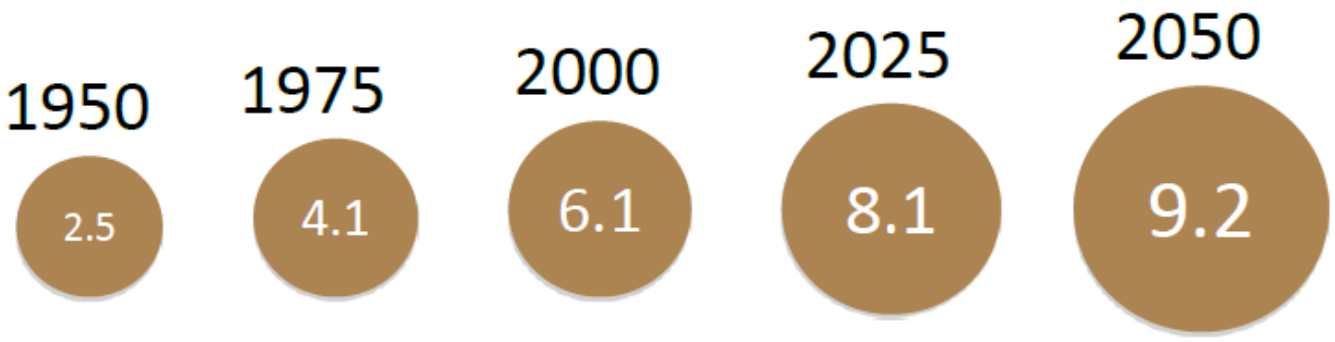
There are opportunities



World population growth (billion) (UN)

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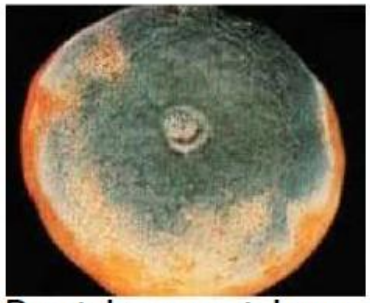
There are opportunities

Algae ($10+ bil)



Post harvest losses ($300 bil)

Sucking insects ($5 bil)

Weeds ($40+ bil)

Stress & Fertilizer Efficiency ($500+ bil)

Plant parasitic nematodes ($80 bil)

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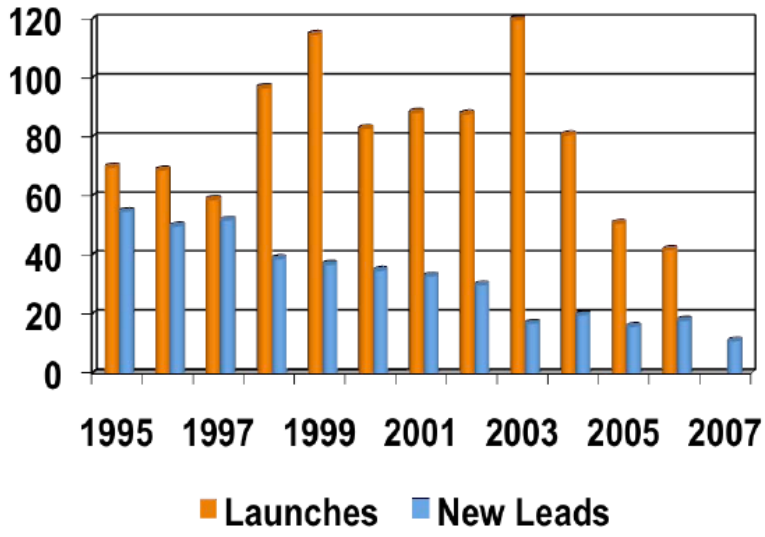
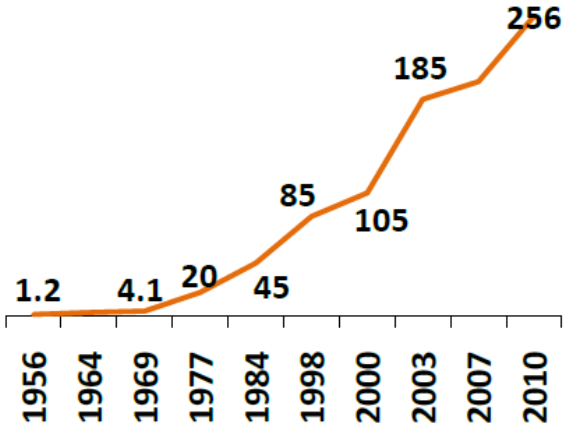
There are opportunities

New Chemistries



Only one new chemical active ingredient was approved by the EPA in 2009

Cost to Develop a New Synthetic Chemical ($Mil)



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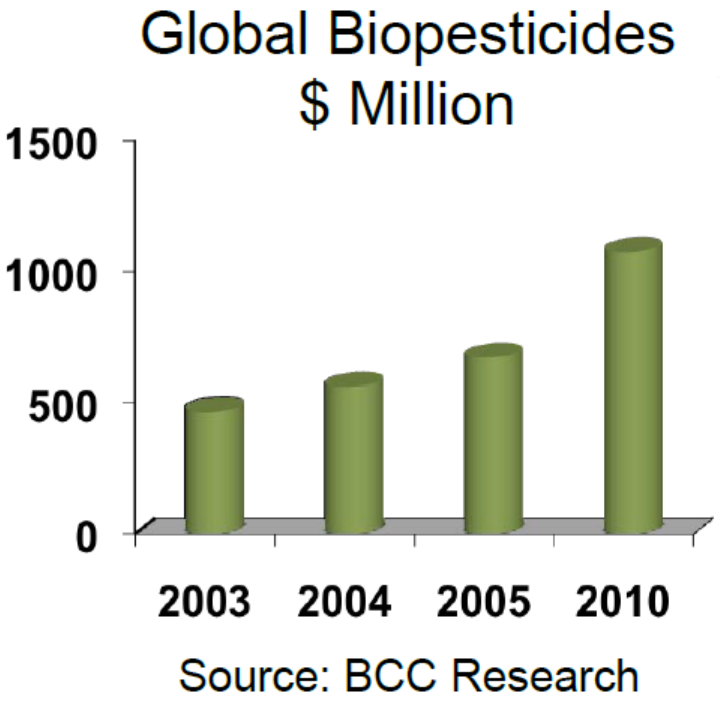
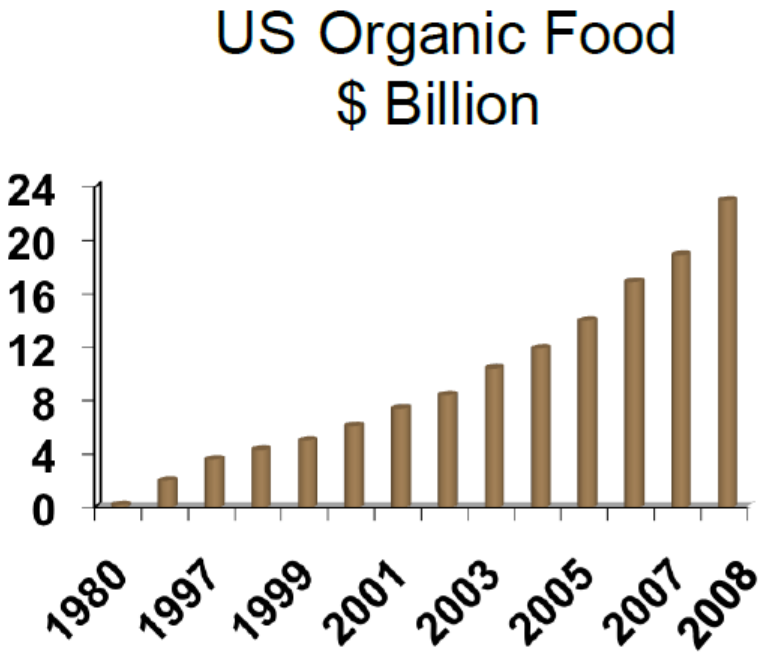
There are opportunities

New Biopesticides

12 biopesticides EPA-registered in 2009



Source: BCC Research



Source: Organic Trade Association

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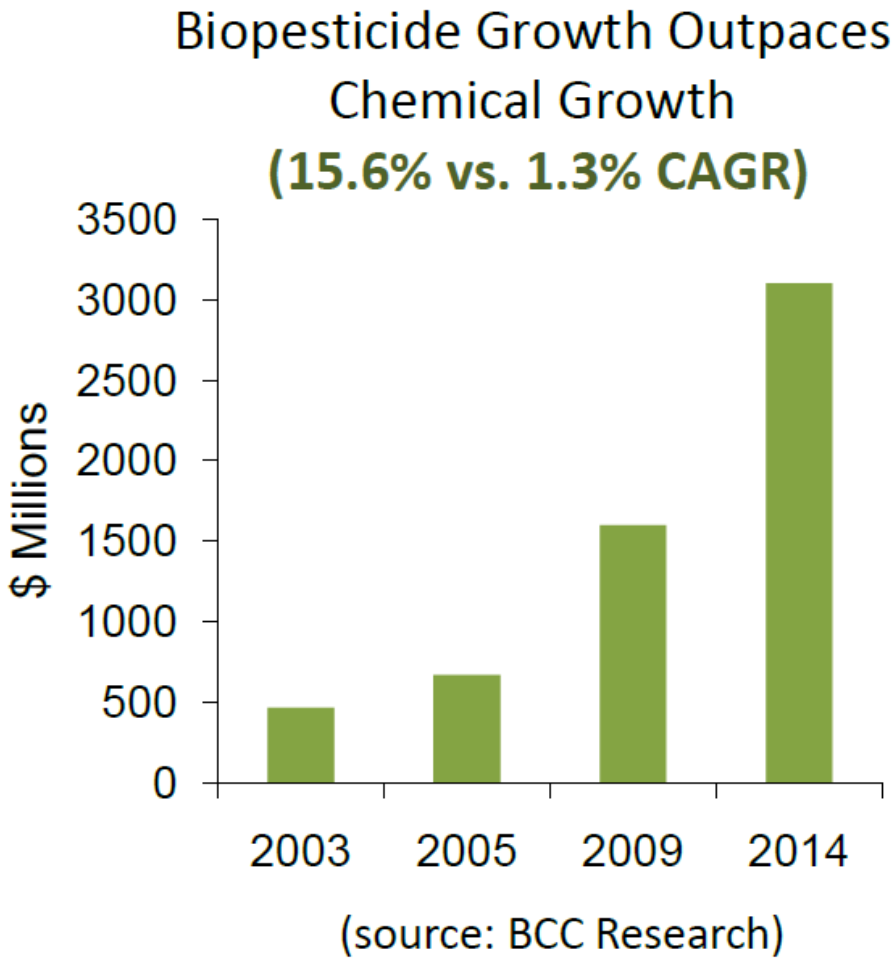
There are opportunities



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There are opportunities

>50 year history of safe use

- All registered biopesticides registered for food use are exempt from tolerance (can use right up to harvest)
- Most have very low toxicity (>5000 mg/kg rat oral, dermal, inhalation)
- Non toxic mode of action; most are soft on beneficials
- Most have 4-hour (EPA's minimum) re-entry period
- Do not contaminate ground and surface water
- Are not ozone disruptors; do not emit VOCs
- Highly biodegradable - do not persist in the environment
- Use the safest (often food grade) inerts (4a and 4b inerts)

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The Chemical v. Biological Paradigm

There is the persistence of a chemical paradigm for pest control products that undervalues biologicals and undermines their development.

Compared to chemical pesticides, biologicals generally fail in areas such as speed of kill, storage, range of targets, ease of use, distribution, and cost.

Source: *Alternative Paradigms to Commercialization of Biological Pesticides,* Experiment Station Committee on Policy - Biological Control Working Group (ESCOP-WGBC) and Rutgers University, New Brunswick, New Jersey, May 31 - June 2, 1998.

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The Chemical v. Biological Paradigm

"Our charge is to think risk taking, think unconventionally, but above all think of new paradigms for biological control."

Source: *Alternative Paradigms to Commercialization of Biological Pesticides,* Experiment Station Committee on Policy - Biological Control Working Group (ESCOP-WGBC) and Rutgers University, New Brunswick, New Jersey, May 31 - June 2, 1998.

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Crop Protection Company Landscape

The Big Six	• $3-8 billion; GM crops and synthetic chemicals • Monsanto, DuPont, Dow, Syngenta, Bayer, BASF • Focus - Large row crops; limited biopesticide R&D • Biopesticide acquisitions and leveraging global sales force to sell others' biopesticides
Generic Suppliers	• $100 million-$2 billion; limited Biopesticide R&D • Arysta, Makhteshim, Nufarm, UPI, Valent/Sumitomo, Advan/Sipcam, Gowan, Cheminova • Leverage sales force to sell others' biopesticides
Biopesticides	• 0-$180 million; Microbials, pheromones, plant oils • Valent Bio, Becker Underwood, Certis, Arysta, Shin-etsu, Novozymes, Suterra, AgraQuest, Plant Health Care, Bioworks, Prophyta, MBI, Pasteuria, Exosect, EcoSmart, etc... • Some discovery/screening; Most in-license

Some failed industry models

EcoScience **Entotech** **Biosys**

Ecogen **Eden Biosciences**

Mycotech **Eco Soil**

Some successful industry models

Valent Biosciences

Certis USA

Bayer Crop Sciences

Becker Microbials

Becker-Underwood

BioWorks

AgraQuest

JET Harvest Solutions

Prophyta Biologischer Pflanzenschutz

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Is the current commercial model the only viable approach to utilization of microbial biopesticides?

Yes and No…

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Costs and models for registration and marketing of biologicals.

System	Steps required	Approximate costs/step	Time to significant market penetration
Full-scale registration and production—the chemical pesticide model	1. Identification of good agent 2. Development of production and formulation system 3. Patenting of strain and/or process 4. Toxicology and other testing 5. Registration 6. Building large-scale production system 7. Nationwide or international marketing	1,2. $100,000 3. Up to $200,000 for international coverage, at least $30,000 for one country 4. At least $500,000 5. $100,000 6. Up to $3-4 million 7. $2-3 million Total: up to $8 million	3 to 6 years
Biofertilizer, inoculant, or plant strengthening agent	1. Discovery of a good agent 2. Development of production and formulation system 3. Patenting of strain and/or process 4. Building large-scale production system 5. Nationwide or international marketing	1,2. $100,000 3. Up to $200,000 for international coverage, at least $30,000 for one country 4. Up to $1 million 5. $0.5 million Total: $1.8 million	1 to 2 years
Local production	Discovery of a good strain	$100,000 Total: $100,000 or less	Less than 1 year
Government sponsored or produced agents	Depends upon governmental direction and philosophy	Unknown	Unknown

Source: Harmon, Gary L., *Changing Models for Commercialization and Implementation of Biocontrol, in the Developing and the Developed World,* Plant Disease / Vol. 94 No. 8, pgs. 928-939

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The challenge to public researchers and institutions regarding commercialization is:

At some point the basic research has to lead to a decision…

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So, how do we make biopesticides work better?

- Use them for Resistance Management
- Rotations and Alternations; Tank mixes
- Use them Early season - low pest pressure
- Use them Late season - short pre harvest interval; manage residues for export.
- Use them during critical field events and to save labor costs - short re-entry intervals get you back in the field

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So, how do we make biopesticides work better?

IPM

Development of biological pesticides does not drive Integrated Pest Management.

IPM and its adoption for pest control and crop protection provide opportunities for integration of biological pesticides…

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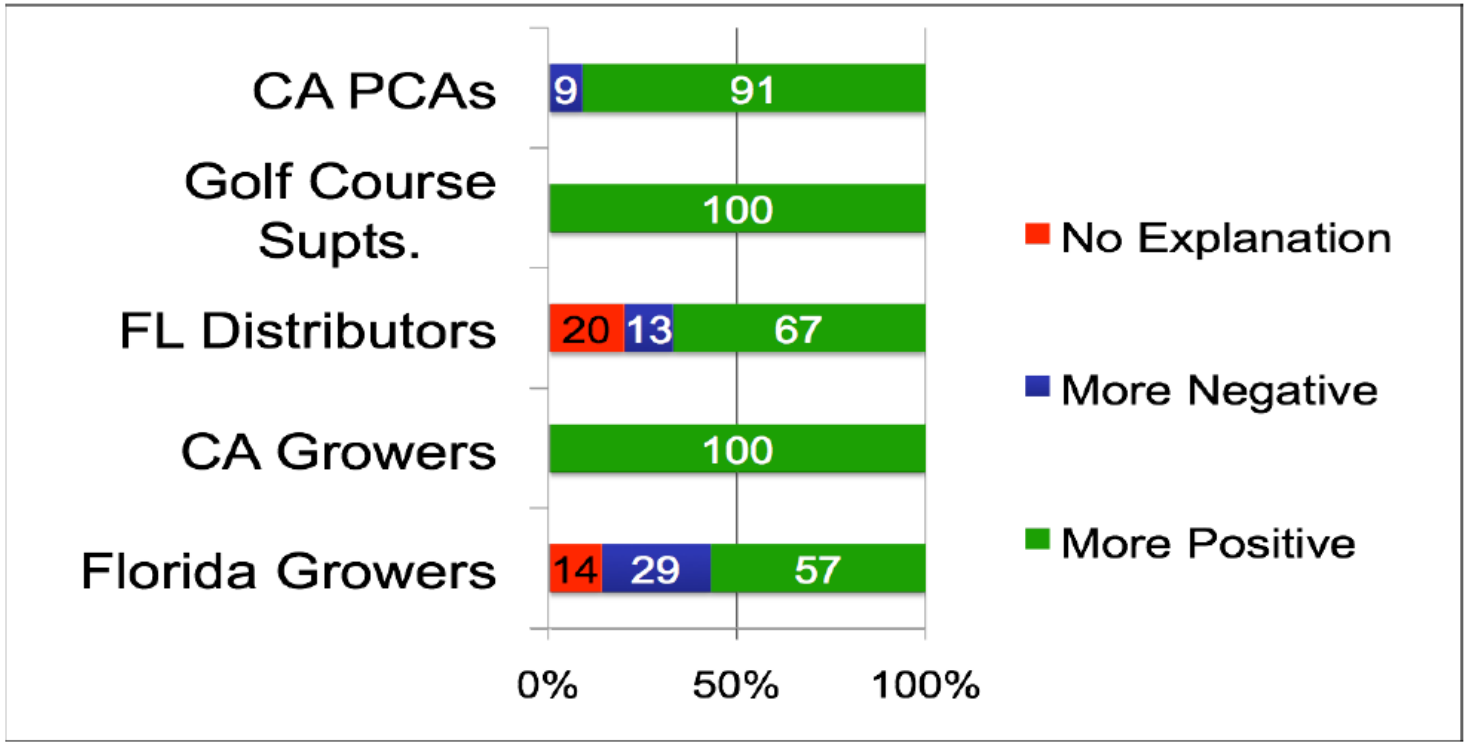
So, how do we make biopesticides work better?

BPIA 2008 Survey: Perception Change



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BPIA's Strategies for Growth of the use of biological pesticides

MISSION

❖Improve the global acceptance of biopesticides as having a strong value proposition.

❖Facilitate the successful development, commercialization, and adoption of biopesticides.

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BPIA's Strategies for Growth of the use of biological pesticides

PURPOSE

❖Promote industry standards for biopesticides.

❖Communicate the value of biopesticides in agriculture, forestry, turf and ornamental, public health, consumer, and other target markets.

❖Develop collaborative working relationships with the authorities that regulate biopesticides **and become a resource to these authorities in order to ensure timely, predictable, transparent, and appropriate registration and regulatory requirements.**

❖Become a leading source of information to key influencers who impact acceptance, commercialization, and adoption of biopesticides.

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BPIA's Strategies for Growth of the use of biological pesticides

OPERATING PRINCIPLES*

❖Products that are supported have appropriate EPA, PMRA, EU or other equivalent registrations.

❖Proper product stewardship at all levels of the value chain:

a. Processes for maintaining product quality integrity and resolving product complaints

b. Scientifically valid efficacy tests supporting claims and promotions

c. Commercially acceptable product efficacy levels in target geography with minimal field trial variability

d. Testimonials from customers and key influencers attesting to efficacy claims and satisfaction with product

* These guiding principles are expected to be followed by all members of BPIA and are a condition of membership. Signed initial membership applications include these guiding principles as will all membership renewals.

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BPIA - Our 2010 Theme

“The Value of Biopesticides in Resistance Management”

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BPIA - Our 2011 Theme

“Maximum Residue Limits (MRLs) and the Impact of Biological Pesticides”

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So, how do we with BPIA intend to encourage greater development and adoption?

- Academic researchers
- Governments and their agencies
- Universities/extension
- The private sector (grocers, food processors, restaurant chains, etc…)
- Growers (conventional and organic)

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Thank you!

BPIA

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